PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Batra et al.	)	Examiner: Not Yet Assigned
Serial No.: Not Yet Assigned (Continuation application of USSN 09/312,617)	)	Previous Examiner: Sharareh, S.
Docket No.: 20243CA	)	Art Unit: Not yet assigned
Express Mailed: June 29, 2001	)	Previous Art Unit: 619
For: "COMPRESSED TABLET FORMULATION"	)	

EXPRESS MAIL CERTIFICATE
DATE OF DEPOSIT June 29, 2001
EXPRESS MAIL NO. EI523104635US
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL, "POST OFFICE TO ADDRESSEE" BEFORE 5 P.M. ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231.
SIGNED BY [signature]
DATE 6/28/01

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Applicants request entry of this amendment prior to examination of the above-identified application, which is a Rule 53(b) continuation of USSN 09/312,617. Please amend the above-identified application as follows:

IN THE SPECIFICATION:

Please insert the following paragraph on page 1 after the Title:

-- This application is a continuation of US Serial No. 09/312,617, filed January 17, 2001, which is a continued prosecution application under 37 C.F.R. § 1.53(d) of US Serial No. 09/312,617, filed May 17, 1999, now abandoned, which claims the benefit of US Provisional Application No. 60/086,921, filed May 27, 1998.--

Replace the fourth paragraph on page 7 with the following paragraph:

-- The formulation also is bioequivalent to a capsule with a smaller dose (200 mg), and more bioavailable than other tablet compositions. The advantages over the capsule include robust processing and sorting steps, smaller size with a larger dose, and market preference. The

tablet composition also overcomes the expected loss of crystallinity of efavirenz by adding the lactose extra-granularly while maintaining the dissolution profile.--

IN THE CLAIMS:

Please amend claims 1 as follows:

1. (amended) A compressed tablet comprising: efavirenz, filler/disintegrant, superdisintegrant, binder, surfactant, diluent/compression aid, lubricant, and solvent, wherein efavirenz is crystalline and is from about 1 to about 75% by weight of the total composition of the compressed tablet.

Please add the following new claims 24-41:

24. (new) The compressed tablet as recited in Claim 1, wherein efavirenz is present in an amount of 300 mg.

25. (new) The compressed tablet as recited in Claim 1, wherein efavirenz is present in an amount of 600 mg.

26. (new) A compressed tablet comprising: efavirenz, filler/disintegrant, superdisintegrant, binder, surfactant, diluent/compression aid, lubricant, and solvent, wherein efavirenz is crystalline and is about 50% by weight of the total composition of the compressed tablet.

27. (new) The compressed tablet as recited in Claim 26, wherein efavirenz is present in an amount of about 300 mg.

28. (new) The compressed tablet as recited in Claim 26, wherein efavirenz is present in an amount of about 600 mg.

29. (new) The compressed tablet as recited in Claim 26, wherein the solvent comprises: water, ethanol or mixtures thereof.

30. (new) The compressed tablet as recited in Claim 29, wherein the filler/disintegrant is a microcrystalline cellulose.

31. (new) The compressed tablet as recited in Claim 30, wherein the superdisintegrant is a croscarmellose sodium.

32. (new) The compressed tablet as recited in Claim 31, wherein the croscarmellose sodium is about 5% by weight of the total composition of the compressed tablet.

33. (new) The compressed tablet as recited in Claim 31, wherein the binder is a hydroxypropyl cellulose.

34. (new) The compressed tablet as recited in Claim 33, wherein the surfactant is a sodium lauryl sulfate.

35. (new) The compressed tablet as recited in Claim 34, wherein the filler/compression aid is a lactose hydrous spray dried.

36. (new) The compressed tablet as recited in Claim 35, wherein the lubricant is a magnesium stearate.

37. (new) A compressed tablet comprising: efavirenz, filler/disintegrant, superdisintegrant, binder, surfactant, diluent/compression aid, lubricant, and solvent; wherein efavirenz is crystalline and is from about 1 to about 75% by weight of the total composition of the compressed tablet; and wherein the compressed tablet is prepared via wet granulation in which efavirenz, filler/disintegrant, superdisintegrant, binder, and surfactant are blended intragranularly, and filler/compression aid and lubricant are added extragranularly.

38. (new) The compressed tablet as recited in Claim 37, wherein efavirenz is about 50% by weight of the total composition of the compressed tablet.

39. (new) The compressed tablet as recited in Claim 37, wherein efavirenz is present in an amount of about 300 mg.

40. (new) The compressed tablet as recited in Claim 37, wherein efavirenz is present in an amount of about 600 mg.

41. (new) The compressed tablet as recited in Claim 37, wherein:
the filler/disintegrant is a microcrystalline cellulose;
the superdisintegrant is a croscarmellose sodium;
the binder is a hydroxypropyl cellulose;
the surfactant is a sodium lauryl sulfate;
the filler/compression aid is a lactose hydrous spray dried; and
the lubricant is a magnesium stearate.

REMARKS

Applicants request examination of the application as amended herein, which is a Rule 53(b) continuation of US Serial No. 09/312,617, filed January 17, 2001.

Information on related applications has been inserted on the first page after the title.

The fourth paragraph on page 7 of the specification has been amended to correct an inadvertent and obvious typographical error in the word "expected".

Original claims 17-23 have been canceled as set forth in the filing papers of the subject application. Claim 1 has been amended herein, and new claims 24-41 have been added. Accordingly, the application as amended herein contains claims 1-16 and 24-41. Support in the specification and original claims for amended claim 1 and the new claims includes:

Claim	Support
1	page 2, lines 18-19; original claim 1
24	page 2, line 21; page 5, table
25	page 2, lines 21-22
26	page 2, lines5-6
27	page 2, line 21; page 5, table
28	page 2, lines 21-22
29	original claim 8
30	original claim 9
31	original claim 10
32	page 5, table
33	original claim 11
34	original claim 12
35	original claim 13
36	original claim 14
37	page 2, line 8; page 5, lines 4-17; page 12 (Scheme 5); and pages 21-22 (Example 8)
38 - 40	see above entries for claims 24-26
41	original claims 9-15

No new matter has been introduced by any of the foregoing amendments to the specification and claims. It is noted that the recitation of the amount of efavirenz in the compressed tablet of claim 1 has been broadened.

Marked up versions of the amended paragraph in the specification and the amended claims explicitly showing the added and deleted matter appear after the Remarks.

The application is believed to be in condition for allowance and passage to issue is requested. The Examiner is invited to telephone the undersigned should any minor matters need to be resolved before a Notice of Allowance can be mailed.

Respectfully submitted,

By Kenneth R. Walton

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Date: June 28, 2001

Marked up versions of the amended paragraph in the specification and the amended claims are as follows, wherein an underline denotes added material and a set of brackets denotes deleted material:

IN THE SPECIFICATION

The fourth paragraph on page 7:

-- The formulation also is bioequivalent to a capsule with a smaller dose (200 mg), and more bioavailable than other tablet compositions. The advantages over the capsule include robust processing and sorting steps, smaller size with a larger dose, and market preference. The tablet composition also overcomes the expected loss of crystallinity of efavirenz by adding the lactose extra-granularly while maintaining the dissolution profile.--

IN THE CLAIMS

1. (amended) A compressed tablet comprising: efavirenz, filler/disintegrant, superdisintegrant, binder, surfactant, diluent/compression aid, lubricant, and solvent, wherein efavirenz is crystalline and is from about 1 to about 75% [50%] by weight of the total composition of the compressed tablet.